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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HOWREY SIMON ARNOLD & WHITE, LLP  
BOX NO. 34  
1299 PENNSYLVANIA AVENUE, NW  
WASHINGTON DC 20004-2402

EXAMINER

MORAN, M

ART UNIT	PAPER NUMBER
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1631

*28*

DATE MAILED:

07/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/942,369</b>	Applicant(s) <b>Chen et al</b>
	Examiner <b>Marjorie Moran</b>	Group Art Unit <b>1631</b>

Responsive to communication(s) filed on Apr 10, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 20-24 and 26 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 20-24 and 26 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 11, 16

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In view of the new rejections set forth below, over prior art not previously set forth, the finality of the office action mailed 4/28/99 is hereby withdrawn, prosecution of claims 20-24 and 26 is reopened, and the appeal filed 4/10/00 is hereby dismissed.

***Claim Rejections - 35 USC § 103***

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Claims 20-24 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of LIBMAN *et al.* (H)

Applicant's arguments with respect to claims 20-25 and 27-30 have been considered but are moot in view of the new ground(s) of rejection. The arguments presented in the appeal brief of 4/10/00 are addressed below.

Applicant claims a method of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents wherein portions of a biological sample are separately added to compartments of an assay device which comprise, separately, a medium capable of sustaining growth of total microbial organisms, a uropathogenic specific medium, and an antimicrobial susceptibility interpretation medium, then examining the different compartments to determine presence and susceptibility of the urinary pathogens. In claim 21, applicant limits his biological sample to urine. In claims 22-23, he limits the pathogens to primary gram negative urinary pathogens, specifically Enterobacteriaceae. In claims 24-25, applicant limits his pathogens to specific species.

JOHNSON teaches a process (method) for detecting and determining the susceptibility of specific microorganisms to antibiotics wherein a clinical (urine) sample is added to separate wells of a microtiter plate, which wells comprise a selective culture medium or blends of the selective culture medium and known antibiotics, the plate is cultured, then the wells examined for growth of microorganisms (col. 10, line 45-col. 12, line 2 and col. 7, lines 33-36).

JOHNSON further teaches that his method and device may be used to analyze urinary pathogens, specifically *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella*, *Enterobacter*, and *Proteus* spp. (col. 3, lines 31-36). JOHNSON also teaches that his sample may be urine, blood or spinal fluid, and that growth in individual growth wells permits a positive test for indication of organisms (col. 7, lines 39-46). JOHNSON does not specifically teach a medium capable of sustaining growth of total microbial organisms.

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LIBMAN teaches a device and method for detecting contaminating microorganisms (pathogens) in a urine sample wherein the sample is cultured on two or more different media, selective and nonselective (col. 3, lines 64-67). LIBMAN teaches that his selective media are "well-known differential media" and are "ideal for enumerating and presumptively identifying urinary flora", and further teaches that common gram negative organisms (responsible *for more than 90% of urinary tract infections*) can be identified readily with his selective media (emphasis added by the examiner, col. 4, lines 1-15).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the nonselective medium of LIBMAN in the method of JOHNSON where the motivation would have been to provide a positive control for microorganismal growth, as suggested by JOHNSON. It would further have been obvious to detect gram negative organisms responsible for more than 90% of UTI's in the method of JOHNSON using the selective media taught by LIBMAN where the motivation would have been to determine the presence (and susceptibility) of the majority of microorganisms (i.e. over 90%) known to contribute to or cause UTI's in order to identify the causative organisms and to determine an appropriate course of treatment, as suggested by both LIBMAN (col. 2, lines 48-53) and JOHNSON (col. 3, lines 30-39). One skilled in the art would reasonably have expected success in incorporating the selective and nonselective media of LIBMAN in the method of JOHNSON because JOHNSON teaches sustenance of growth of total microbial organisms, which implies use of a nonselective medium, and because JOHNSON specifically teaches use of selective media.

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In response to the argument that the prior art does not teach a “uropathogenic specific medium”, defined as a medium which is selective for growth of primary gram negative uropathogens, said uropathogens being those which cause 85-90% of UTI’s, the examiner points to the teaching of LIBMAN, above, for “selective media” which can be used to readily identify “gram negative organisms” responsible for “more than 90% of urinary tract infections”. Although LIBMAN does not use the terms “uropathogen” or “uropathogenic specific medium”, his definition of gram negative organisms which are responsible for more than 90% of UTI’s is clearly congruent with applicant’s definition for uropathogens, therefore a “specific medium” for growth of such organisms is a “uropathogenic specific medium”. It is noted that applicant further defines his medium on page 13 of the appeal brief as one which selects against non-primary gram negative bacteria such as *Bacteroides*, *Neisseria*, etc. A teaching for a specific medium which inhibits or prevents the growth of bacteria other than primary gram negative bacteria is found in the originally filed specification on page 12; however, no teaching or recitation is found in the original specification or claims for specific exclusion of *gram negative* bacteria which are not primary gram negative uropathogens, nor is any exclusion of particular organisms recited anywhere. It is further noted that LIBMAN does teach that his device may be used to detect *Neisseria* (col. 1, lines 56-63); however, LIBMAN teaches that the “selective media” for use in detecting *Neisseria* (e.g. a gonococcal medium) is different from those taught as selective media for detection of his gram negative organisms (col. 4, lines 44-53). Applicant further argues on page 15 of the appeal brief that the prior art does not elucidate (teach or make

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obvious) a medium containing multiple antibiotics which selects for multiple organisms, as set forth on page 19 of the specification. The claims do not recite antibiotics in a selective medium. The claims do not recite any limitations to the medium at all with regard to its composition. As set forth in the Advisory Action of 7/21/99, applicant was invited to amend the claims to add limitations regarding antibiotics, etc. in the selective medium in order to overcome the prior art then of record; however, no such amendments were filed. Applicant also argues that his method may be used with nonsterile urine samples. Both JOHNSON (col. 7, lines 33-50) and LIBMAN (col. 4, lines 54-64) teach detection of pathogens in nonsterile urine samples.

For all of the reasons set forth above, claims 20-24 are obvious.

Claim 26 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of LIBMAN *et al.* (H) as applied to claim 20 above, and further in view of BROCCO (E).

Applicant's arguments with respect to claim 26 have been considered but are moot in view of the new ground(s) of rejection. All previous arguments with respect to claim 26 have been addressed in previous office actions; no further arguments regarding claim 26 were set forth in the appeal brief of 4/10/00.

Applicant claims a method of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents, as set forth

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above. Applicant further limits the antimicrobial agents to amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

JOHNSON in view of LIBMAN make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents using a nonspecific medium and a medium specific for urinary gram negative pathogens, as set forth above. JOHNSON in view of LIBMAN do not specifically teach amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

As previously set forth in the office action of 11/9/98, BROCCO teaches a method of determining susceptibility of uropathogens, specifically *Staphylococcus* and *Streptococcus*, to amoxicillin and a clavulanic acid mixture (p. 5, line 8-p. 6, line 7 and p. 9, line 4-p. 10, line 15).

It would have been obvious at the time of invention to include the amoxicillin and clavulanic acid of BROCCO as antimicrobial agents in the method of JOHNSON in view of LIBMAN where the motivation would have been to test susceptibility of microorganisms, specifically urinary pathogens, to any known antibiotics, as suggested by JOHNSON, in order to determine an appropriate course of treatment for a subject infected with the microorganisms. For these reasons, claim 26 is obvious.

### *Conclusion*

Claims 20-24 and 26 are newly rejected.

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Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*marj*  
Marjorie A. Moran  
Patent Examiner  
Art Unit 1631

*MPW*  
MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600